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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,975	07/14/2003	Mark D. Soll	MER 03-009	8586

33928 7590 06/20/2008

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EXAMINER	
PRYOR, ALTON NATHANIEL	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
06/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,975	SOLL ET AL.	
	Examiner	Art Unit	
	ALTON N. PRYOR	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-63* is/are pending in the application.

4a) Of the above claim(s) *3,4,8,9,11-13,15,16,18-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6,7,10,14 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 4/16/08 have been fully considered but they are not persuasive. See discussion below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2,6,7,10,14,17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Meinke et al (WO 9629073; 9/26/96) and Cleverly et al (USAN 2004/0037869; 2/26/04). Meinke teaches a formulation comprising the elected t-butyl nodulisporamide (where R3 = OH; R1 and R2 together is =O; R3,R4 = OH, R5 = H; and R7 = fragment having double bond with R10 being the t-butyl amide group) and liquid carriers such as propylene glycol. Meinke also teaches that the formulation can be formulated as a spot on formulation. However, whether the formulation is a spot on or an oral formulation does not matter since a statement of intended use in a claim to a formulation does not carrier patentable significance. See abstract, page 34 line 8 – page 37 line 23, claim 13. Meinke does not teach 1) an exemplification of the elected t-butyl Nodulisporamide, 2) the combination of the elected t-butyl nodulisporamide with propylene glycol as the carrier and a crystallization inhibitor in a composition. However, it would have been obvious to one having ordinary skill in the art to have made the elected t-butyl nodulisporamide and combine it with propylene glycol to arrive at a

formulation as claimed. One would have been motivated to make the elected t-butyl nodulisporamide compound since claim 13 of WO '073 suggests Rx as t-butyl. One would have been further motivate to combine the elected t-butyl nodulisporamide with propylene glycol since WO '073 at page 35 line 26 suggests the combination. With respect to the crystallization inhibitor Cleverly teaches a formulation that can contain numerous pharmaceutical agents including nodulisporic acid derivatives. See paragraph 62. Cleverly teaches that the formulation can be used as a pour-on formulation. See paragraph 175. Cleverly teaches that the formulation can further comprise benzyl alcohol (crystallization inhibitor) and / or polyoxyethylene sorbitan fatty acid esters (crystallization inhibitor). See paragraphs 186-187. It would have been obvious to one having ordinary skill in the to combine the prior art compositions since they are both nodulisporic acid derivatives such as nodulisporamide. Note applicant elects transcutol as the carrier for the elected t-butyl nodulisporamide. However, applicant does not show that transcutol would have provided a result different from that obtained using another structurally similar carrier. For this reason, Meinke makes the elected composition comprising t-butyl nodulisporamide and transcutol obvious.

Response to Applicants' Argument

Applicants argue:

1) Meinke does not teach or suggest a crystallization inhibitor in a spot-on formulation; Therefore, Meinke does not teach or suggest all claim limitations.

2) Meinke teaches propylene glycol use in a possible parental administration rather than as a vehicle for a spot-on formulation.

2) Cleverly does not disclose or suggest a crystallization inhibitor system comprising a film-forming agent and a surfactant in a spot-on formulation.

3) Cleverly does not disclose or teach a spot-on formulation, but rather teaches oral formulations comprising nodulisporic acid derivatives.

4) Cleverly pertains to benzyl alcohol as a preservative rather than as a crystallization inhibitor in the formulation as claimed.

The Examiner argues:

While it is true that Meinke does not teach a spot-on formulation comprising a crystallization inhibitor and nodulisporic acid derivatives, Meinke does teach that the composition can be formulated as a spot-on formulation (page 34 lines 8-24) and Cleverly suggests that a preservative such as benzyl alcohol can be added to a nodulisporic containing composition (paragraph 186), and Cleverly further teaches that the composition can be formulated into a pour-on (spot-on) formulation (paragraph 175). The teachings make it obvious to make a composition comprising a nodulisporic acid derivative and benzyl alcohol. Note while it is true that Cleverly does name benzyl alcohol as a preservative rather than a crystallization inhibitor, the naming of the ingredient by function (preservative or crystallization inhibitor) has no patentable weight in a claim drawn to a composition. The fact remains that the combination of Meinke with Cleverly suggests a formulation containing nodulisporic acid derivative and benzyl alcohol (crystallization inhibitor – paragraph 186) as presently claimed. Cleverly also teaches that the composition can contain surfactants/film-forming agents such as polyoxyethylene sorbitan fatty acid esters or polyvinyl alcohol to prevent crystallization

(paragraph 187). Thus the combination of the references makes obvious a spot-on formulation comprising a nodulisporic acid derivative, crystallization inhibitor (benzyl alcohol) and film-forming agent (polyoxyethylene sorbitan fatty acid esters or polyvinyl alcohol) as presently claimed. Whie it is true that Meinke teaches propylene glycol use in a possible parental administration rather than as a vehicle for a spot-on formulation, this teaching does not rule out the possibility of a spot-on formulation containing propylene glycol. Note a reference is not required to exemplify all formulation scenarios in order to make obvious an implicit composition being claimed.

New Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2,6,7,14,17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,4 and 5 of copending Application No. 2008/0003282 or 11/580731 in view of Cleverly (USAN 2004/0037869). The claims of USAN '282 are directed to a process of topically applying a parasiticide formulation comprising 1,2-diazole to an animal. Claim 4 of USAN '282 recites that an additional parasiticide such as nodulisporic acid derivative can be added to the formulation. At paragraphs 24-28 and 102 USAN '282 discloses that the topical application can be a spot-on formulation. USAN '282 does not make claim to an invention comprising a film-forming agent and a crystallization inhibitor. However, Cleverly suggests a formulation containing nodulisporic acid derivative and benzyl alcohol (crystallization inhibitor – paragraph 186) as presently claimed. Cleverly also teaches that the composition can contain surfactants/film-forming agents such as polyoxyethylene sorbitan fatty acid esters or polyvinyl alcohol to prevent crystallization (paragraph 187). Thus the combination of the references makes obvious a spot-on formulation comprising a nodulisporic acid derivative, crystallization inhibitor (benzyl alcohol) and film-forming agent (polyoxyethylene sorbitan fatty acid esters or polyvinyl alcohol) as presently claimed.

Claims 1, 2,6,7,14,17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,8 and 9 of copending Application No. 12/119150 in view of Cleverly (USAN 2004/0037869). The claims of USAN '150 are directed to a pesticide formulation comprising azole. Claim 8 of USAN '150 recites that an additional pesticide can be added to the formulation. USAN

‘150 at paragraphs 21 and 24 recite that the pesticide composition can be formulated as a spot-on composition and at paragraph 38 USAN '150 it is disclosed that the additional pesticide can be a nodulisporic acid derivative. USAN ‘150 does not make claim to an invention comprising a film-forming agent and a crystallization inhibitor. However, Cleverly suggests a formulation containing nodulisporic acid derivative and benzyl alcohol (crystallization inhibitor – paragraph 186) as presently claimed. Cleverly also teaches that the composition can contain surfactants/film-forming agents such as polyoxyethylene sorbitan fatty acid esters or polyvinyl alcohol to prevent crystallization (paragraph 187). Thus the combination of the references makes obvious a spot-on formulation comprising a nodulisporic acid derivative, crystallization inhibitor (benzyl alcohol) and film-forming agent (polyoxyethylene sorbitan fatty acid esters or polyvinyl alcohol) as presently claimed.

Claims 1, 2,6,7,14,17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,4 and 5 of copending Application No. 2005/0234119 or 10/826105 in view of Cleverly (USAN 2004/0037869). The claims of USAN ‘119 are directed to a process of topically applying a parasiticide spot-on formulation comprising 1,2-diazole to an animal. Claim 4 of USAN ‘119 recites that an additional parasiticide such as nodulisporic acid derivative can be added to the formulation. USAN ‘119 does not make claim to an invention comprising a film-forming agent and a crystallization inhibitor. However, Cleverly suggests a formulation containing nodulisporic acid derivative and benzyl alcohol (crystallization inhibitor – paragraph 186) as presently claimed. Cleverly also teaches

that the composition can contain surfactants/film-forming agents such as polyoxyethylene sorbitan fatty acid esters or polyvinyl alcohol to prevent crystallization (paragraph 187). Thus the combination of the references makes obvious a spot-on formulation comprising a nodulisporic acid derivative, crystallization inhibitor (benzyl alcohol) and film-forming agent (polyoxyethylene sorbitan fatty acid esters or polyvinyl alcohol) as presently claimed.

This is a provisional obviousness-type double patenting rejection.

Election Status

The elected invention comprising t-butyl nodulisporamide and transcutol is not allowable. See art rejection above.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alton N. Pryor/
Primary Examiner, Art Unit 1616